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Keep Out FDA: Food Manufacturers' Ability to Effectively Self-Regulate Front-of-Package Food Labeling

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KEEP OUT FDA: FOOD MANUFACTURERS' ABILITY TO EFFECTIVELY SELF-REGULATE FRONT-OF-PACKAGE FOOD LABELING

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Self-regulation works because the industry recognizes it is a privilege, not a right. – Wolfgang H. Reinicke

I. INTRODUCTION TO THE "OBESITY EPIDEMIC"

The headlines on any given day claim that the American "obesity epidemic" continues to worsen.[1] According to these headlines, Americans, both adults and children, are increasingly becoming more obese, are more likely to be diagnosed with diabetes, and will likely prematurely die due to this preventable disease.[2] Numerous private industries, as well as the government, seek to rescue Americans from this crisis.[3] As the obesity epidemic debate intensifies, the call for more government regulation correspondingly grows.[4] There are critics, however, who question the

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[1] *See* Lindsey Tanner, *Americans' Bellies Are Expanding Fast, Study Shows*, Sept. 16, 2014, HUFFINGTON POST, *available at* http://www.huffingtonpost.com/2014/09/16/americans-belly-fat-waistline_n_5832516.html; Amir Kahn, *America Tops List of 10 Most Obese Countries,* U.S. NEWS & WORLD REPORT, May 28, 2014, *available at* http://health.usnews.com/health-news/health-wellness/articles/2014/05/28/america-tops-list-of-10-most-obese-countries; Alice G. Walton, *Still Struggling: U.S. Obesity Rates Largely Unchanged Over Last 10 Years*, FORBES, Feb. 26, 2014, *available at* http://www.forbes.com/sites/alicegwalton/2014/02/26/still-struggling-u-s-obesity-rates-stalled-over-the-last-10-years/.

[2] *Id.*; *see also* Cara L. Wilking & Richard A. Daynard, Ph.D, *Beyond Cheeseburgers: The Impact of Commonsense Consumption Acts on Future Obesity-Related Lawsuits*, 68 FOOD & DRUG L.J. 229, 230 (2013); Emily J. Schaffer, *Is the Fox Guarding the Henhouse? Who Makes the Rules in American Nutrition Policy?*, 57 FOOD & DRUG L.J. 371, 375 (2002).

[3] *See, e.g.*, LET'S MOVE, LEARN THE FACTS, *at* http://www.letsmove.gov/learn-facts/epidemic-childhood-obesity (last visited Feb. 28, 2014) (starting the Let's Move campaign, which is "dedicated to solving the challenge of childhood obesity within a generation.").

[4] Part of this call for government regulation is tied to the correlating increased health costs for obesity-related health care costs. However, according to a 2008 study, "effective obesity prevention leads to a decrease in costs of obesity-related diseases [but] is offset by cost increases due to diseases unrelated to obesity in life-years gained." Pieter H.M. van Ball et al., *Lifetime Medical Costs of Obesity: Prevention No Cure for Increasing Health Expenditure*, 5 PLOS MEDICINE 242, Abstract, (2008). Thus, the study con-

legitimacy of this epidemic and the need for more regulation.[5] For example, some well-known scholars opine that the obesity numbers are inflated based upon the inaccurate methodology used to categorize a person as obese.[6] Instead, these critics argue that until an appropriate mechanism is developed to identify the obese population with consistent statistics proving there is an epidemic, the current rhetoric is merely an attempt to increase government involvement.[7] In addition, recent studies also indicate that the obesity numbers are decreasing, thereby further questioning the need for more government regulation.[8]

Assuming the "obesity epidemic" exists, the next issue involves identifying its cause. Unsurprisingly, this answer is not only controversial, but also complex with multifaceted reasons for why Americans are more obese than ever before in history. Health experts point to lifestyle choices as one reason for our population's obesity.[9] For example, lifestyle choices such as poor nutrition habits or lack of physical activity both contribute to weight gain.[10] Another reason for obesity may relate to an individual's genetic makeup, as evidenced by studies revealing that genes may affect how and where a person stores fat.[11] Lastly, some experts point to the en-

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cludes that "[o]besity prevention may be an important and cost-effective way of improving public health, but it is not a cure for increasing health expenditures." *Id.*

[5] *See, e.g.*, Paul Campos et al., *The Epidemiology of Overweight and Obesity: Public Health Crisis or Moral Panic?*, 35 INT'L J. EPIDEMIOLOGY, 35, 55-60 (2006) ("Given the limited scientific evidence for any of these [obesity epidemic] claims, we suggest that the current rhetoric about an obesity-driven health crisis is being driven more by cultural and political factors than by any threat increasing body weight may pose to public health."); *see also* Geoffrey Kabat, *Can The Obesity Epidemic Be Reversed – Or Does Obesity Reinvent A New Stage in Human Evolution?*, FORBES, Jan. 6, 2014, *available at* http://www.forbes.com/sites/geoffreykabat/2014/01/06/can-the-obesity-epidemic-be-reversed-or-does-obesity-represent-a-new-stage-of-human-evolution/ ("The powerful societal and cultural changes underlying the obesity epidemic will not be reversed by simplistic regulatory top-down actions.").

[6] *See, e.g.*, *Mathematicians Find We've Been Calculating Body Mass Index Wrong*, THE TELEGRAPH, Jan. 21, 2013, *available at* http://www.businessinsider.com/mathematicians-find-weve-been-calculating-body-mass-index-wrong-2013-1 (discussing Nick Trefethen, renowned mathematician from Oxford University, who finds the current BMI calculation inaccurate and misleading to the public).

[7] *See* Campos, *supra* note 5, at 55.

[8] *See, e.g.*, CTR. DISEASE CONTROL, PROGRESS ON CHILDHOOD OBESITY: MANY STATES SHOW DECLINES (Aug. 2, 2013), *available at* http://www.cdc.gov/VitalSigns/pdf/2013-08-vitalsigns.pdf (reporting that childhood obesity rates declined in 19 of 43 states, increased for 3 of 43 states, and stayed the same for 21 of 43 states studied from 2008 to 2011) [hereinafter CDC PROGRESS ON CHILDHOOD OBESITY].

[9] *See* Randy Dotinga, *Average Obese Woman Gets Just 1 Hour of Exercise a Year: Study*, HEALTHDAY, Feb. 20, 2014, *available at* http://consumer.healthday.com/fitness-information-14/aerobics-or-calisthenics-health-news-239/average-obese-woman-gets-just-1-hour-of-exercise-per-year-study-684974.html (citing Mayo Clinic Proceedings study that determined obese women get only one hour of vigorous exercise per year).

[10] *See, e.g.*, Katja Pahkala et al., *Body Mass Index, Fitness and Physical Activity from Childhood Through Adolescence*, 47 BR. J. SPORTS MED. 71, 71 (2013) (discussing the importance of childhood fitness activity and its correlation to obesity).

[11] *See* Claude Bouchard, *Childhood Obesity: Are Genetic Differences Involved*, 89 AM. J. CLIN. NUTRITION 1494S, 1494S (2009).

vironment as contributing to a lifestyle that leads to obesity.[12] Within this concept of environment, health experts point to food advertising, fast food restaurants, larger portion sizes, and hectic work schedules as potential causes of obesity.[13]

Regarding food advertising, these experts claim that the food industry is directly responsible for creating advertising that encourages consumers to purchase unhealthy food products, thus furthering the obesity crisis.[14] These food industry critics equate the conduct of the food industry to the tobacco industry, by comparing the marketing strategies, maximum profit interests, and strong lobbying efforts of each and finding parallel practices of both.[15] Similar to cigarette companies, the critics argue that food companies – which are in business to make money – market and sell products based upon whether the public will purchase them, which may require adding or reducing sugar and fat.[16] Acknowledging that the public is generally aware of the bad health effects of smoking, these critics desire the public to have the same level of awareness regarding poor diet choices and blame the food industry for not only creating foods with minimal nutritional value, but also for misleading the public about the actual nutritional value.[17] Specifically within the realm of advertising, the critics claim the food industry misleads consumers through food labeling, including labeling that occurs on the front-of-the package ("FOP").[18]

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[12] *See, e.g.*, Todd J. Zywicki et al., *Obesity and Advertising Policy*, 12 GEO. MASON L. REV. 979, 980 (2004) (citing the various environmental hypotheses for obesity, including food advertising).

[13] *See* OBESITY CAUSES, HARVARD SCHOOL OF PUBLIC HEALTH, *at* http://www.hsph.harvard.edu/obesity-prevention-source/obesity-causes/ (last visited Feb. 21, 2014).

[14] *See* Marlene B. Schwartz & Kelly D. Brownell, *Actions Necessary to Prevent Childhood Obesity: Creating the Climate for Change*, 35 J. LAW. MED. & ETHICS 78, 79-85 (2007).

[15] *See, e.g.*, MARION NESTLE, FOOD POLITICS, HOW THE FOOD INDUSTRY INFLUENCES NUTRITION AND HEALTH 361 (2002) (discussing how the "similarities between the actions of cigarette companies and food companies are no coincidence").

[16] *Id.* at 362. Critics argue that the industry's focus on making profits drives it to unethically market products that have limited nutritional value. *Id.*

[17] *See id.* at 361-62 (stating that the food industry has used parallel tactics "[i]n the same way that cigarette companies' promotion of smoking raises ethical issues, so does the food industry's promotion of minimally nutritious products and overeating in general").

[18] *See, e.g.*, Melissa M. Card, *America, You Are Digging Your Grave with Your Spoon – Should the FDA Tell You That on Food Labels?*, 68 FOOD AND DRUG L. J. 309, 322-27 (2013) (advocating that the FDA mandate the statement "Warning: this product is high in sugar increasing your risks of becoming obese" be placed on particular products such as "candy bars, sodas, baked goods, trail mixes, and some cereals"). Professor Richard Epstein takes a different approach to food labeling laws; *see* Richard A. Epstein, *What (Not) to Do About Obesity: A Moderate Aristotelian Approach*, 93 GEO. L. J. 1361,1383-86 (2005). Professor Epstein states:

> It takes only one look at greasy and fatty foods to realize that they contain calories that could lead to obesity. The rest of the information is of little help in figuring out what to do, and could easily lead people to make comparisons between this and that food, based on fine differences in labeling, which have little or no consequence for overall behavior and well-being. . . . The government can always intervene. But at this point further intervention can't help. Individual life-

This article focuses exclusively on FOP food labeling and highlights food labeling regulations, with particular attention paid to the absence of FOP labeling laws. In this absence, the food industry has initiated its own set of regulations for FOP labeling, and the article analyzes whether the food industry should be trusted to self-regulate in this important area of food labeling. To be sure, critics argue that the food industry is not capable of such self-regulation – when its true motives are profits, not improving health – and that the government is better equipped to battle the "health crisis." But even without government oversight, the food industry retains a checks-and-balances system in place because consumers who are allegedly misled by FOP labeling may pursue a legal remedy by filing a claim against the food manufacturer. Thus, industry proponents point to self-regulation as an efficient mechanism to avoid the pitfalls of government bureaucracy and emphasize how effective self-regulation has been in numerous other industries.

II. EXISTING FOOD LABELING REGULATIONS

Throughout the last several decades, consumers have increasingly become more aware of the nutritional content of the foods they consume. One potential source of this knowledge may be traced to the labeling found on food products.[19] The impetus for the label goes back to 1990, when Congress enacted the Nutrition Labeling and Education Act (the "NLEA"), which authorized the FDA to regulate nutrition labeling and required food manufacturers to place a label on their foods notifying consumers of particular nutritional information concerning their products.[20] The purpose of the NLEA was to provide consumers with scientifically valid nutritional information to encourage healthier food choices through

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style preferences are too varied, and the science is too muddled for there to be a better answer than the one my parents gave me more years ago than I care to remember: eat a balanced diet, do some exercise, don't smoke and don't drink to excess.

Id. at 1383-86.

[19] A food's label is defined as a "display of written, printed or graphic matter upon the immediate container of any article." 21 U.S.C. § 321(k) (2012). But in addition to the actual food label located on the immediate container of the food product, food labeling also includes labeling that "accompan[ies]" the food. *Id.* § 321(m).

[20] *See* 21 C.F.R. § 101.2 (2014). Recently, the FDA announced its proposed changes to the current design of the required nutrition label that would implement a new label that identifies the amount of any added sugar and more accurately reflects the serving size. *See* U.S. FOOD & DRUG ADMIN., PROPOSED CHANGES TO THE NUTRITION FACTS LABEL, *at* http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm385663.htm (last visited Dec. 3, 2014) [hereinafter FDA PROPOSED CHANGES].

nutrition labeling.[21] The FDA nutrition label regulations, promulgated pursuant to the NLEA, specifically detail the design and type size of the required nutritional panel, as well as where it must be placed on the food product.[22] The FDA has recently proposed changes to the nutrition panel label, which has essentially remained unchanged for the past twenty years.[23] The proposed changes focus primarily on three areas: 1) providing better nutrition information based upon science; 2) updating serving size requirements; and 3) changing the current design to make certain information more prominent.[24]

In addition to regulating all aspects of the nutrition label found on the back of food products, the FDA is also authorized to prescribe whether additional information may appear on a food's label. For example, a manufacturer, although legally required to include a nutrition label on its product, might also voluntarily desire to include other information about its product, in an effort to further educate consumers about the healthy attributes of the product or perhaps to differentiate its product from the competitor's. Such information might include, health, nutrient or structure/function claims, which are all regulated by the FDA.[25] Each of these claims warrant further discussion to appreciate how they fit within the broader context of food labeling laws.

Health claims, where the manufacturer alleges a connection between a "substance" in its product and a disease, require approval from the FDA prior to including the claim on the label.[26] This requirement of prior approval results in fewer health claims appearing on food labels due to the additional burden it places on manufacturers. There are two categories of health claims: authorized; and qualified. The FDA specifies in the regulations which authorized health claims are allowed to be placed on product.[27]

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[21] *See* Nutrition Labeling and Education Act of 1990, Pub. L. No. 101-535, 104 Stat. 2353 (codified at 21 U.S.C. § 343 (2012)).

[22] *See* 21 C.F.R. § 101.1, § 101.2 (2014).

[23] *See* FDA PROPOSED CHANGES, *supra* note 20.

[24] *Id.*

[25] *See* 21 C.F.R. § 101.13, § 101.14. (2014); *see also* Barbara O. Schneeman, *Guidance for Industry and FDA: Dear Manufacturer Letter Regarding Food Labeling* (Jan. 2007), *available at* http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm053425.htm.

[26] 21 U.S.C § 343(r)(2)(A)(i) (2012); *see also* 21 C.F.R. §101.14(a)(2) (2014). Substance is defined as "a specific food or component of food, regardless of whether the food is in conventional food form or a dietary supplement that includes vitamins, minerals, herbs, or other similar nutritional substances." An example of a health claim is "Diets low in saturated fat and cholesterol that include 25 grams of soy protein a day may reduce the risk of heart disease." U.S. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY: A FOOD LABELING GUIDE 81 (Jan. 2013), *available at* http://www.fda.gov/downloads/Food/GuidanceRegulation/UCM265446.pdf.

[27] *See* 21 C.F.R. § 101.72 - 101.83 (2014).

If a manufacturer wants to include an authorized health claim on its product that has not been previously approved by the FDA, the manufacturer must file a petition with the FDA seeking approval for the proposed health claim.[28] In considering whether to approve a petition for an authorized health claim, the FDA considers the following:

> [whether] based on the totality of the publicly available evidence (including evidence from well-designed studies conducted in a manner which is consistent with generally recognized scientific procedures and principles), that there is significant scientific agreement, among experts qualified by scientific training and experience to evaluate such claims, that the claim is supported by such evidence.[29]

A qualified health claim is based upon evidence that is less than the "significant scientific agreement" standard and requires the manufacturer to place a disclaimer statement on the product to notify consumers that the health claim is "qualified."[30] For authorized or qualified health claims, if the manufacturer includes an unapproved health claim on the label, it is deemed "misbranded" and subject to legal action by the FDA.[31]

Manufacturers are also allowed to include certain nutrient content claims on food packaging.[32] Whereas health claims state a connection between a substance and a disease, a nutrient content claim characterizes only a nutrient found in the product.[33] Examples of nutrient content claims are "low in fat" or "high in fiber." However, only those nutrient content claims that have been approved by the FDA and are listed in the regulations may be placed on the product.[34] Even if the nutrient content claim is

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[28] *See* U.S. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY: EVIDENCE-BASED REVIEW SYSTEM FOR THE SCIENTIFIC EVALUATION OF HEALTH CLAIMS – FINAL (Jan. 2009), *available at* http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm073332.htm [hereinafter FDA GUIDANCE FOR INDUSTRY].

[29] 21 U.S.C. § 343(r)(3)(B)(i) (2012). This standard is referred to as the significant scientific agreement standard. *See* § 21 C.F.R. § 101.14 (c) (2014); *see also* Krista Carver, *A Global View of the First Amendment Constraints on FDA*, 63 FOOD & DRUG L. J. 151, 159-60, 180-82 (2008) (providing a comprehensive analysis of how the First Amendment affects the FDA's regulatory scheme, including the *Pearson v. Shalala* case where the Court of Appeals for the District of Columbia Circuit held that the FDA had violated the First Amendment rights of a dietary supplement manufacturer by not allowing health claims with a disclaimer).

[30] *See* FDA GUIDANCE FOR INDUSTRY, *supra* note 28. For example, ConAgra Foods Inc. filed a petition with the FDA on January 27, 2012, seeking approval of a qualified health claim that whole grain consumption reduces the risk of developing type 2 diabetes. ConAgra Foods, Petition for Qualified Health Claim for Whole Grains and Reduced Risk of Diabetes Mellitus Type 2, Docket No. FDA-2012-Q-0242 (Jan. 27, 2012).

[31] *See* 21 C.F.R. § 101.18 (2014).

[32] *See id.* § 101.13(b).

[33] *Id.*

[34] *Id.*

allowed, if there is a nutrient present in the food that is above the FDA prescribed level, the product must include a disclosure statement.[35] Additionally, manufacturers may include a structure/function claim on their packaging.[36] This claim describes the role of a nutrient found in the food that involves a structure or function in the body.[37] Unlike health claims, a manufacturer does not need pre-approval from the FDA prior to including a structure/function claim; however, the manufacturer must make sure that the claim is accurate.[38]

Regarding any information a manufacturer places on its label, the Food Drug and Cosmetic Act ("FDCA") prohibits manufacturers from "misbranding" its products, defined as labeling that "is false or misleading in any particular" manner.[39] If the FDA suspects that a manufacturer has violated the FDCA, it generally sends a warning letter urging the manufacturer to voluntarily correct its action, but if the FDA does not receive a satisfactory response from the manufacturer, it may pursue a formal legal action.[40]

In tandem with the FDA, the Federal Trade Commission ("FTC") is also charged with regulating food activity; whereas the FDA regulates food labeling, as previously discussed, the FTC regulates food advertising.[41] Food advertising does not have "immediate connection with the sale of the product"; thus, by process of elimination, it includes anything that is not "labeling."[42] The Federal Trade Commission Act ("FTCA") empowers the FTC to protect consumers from "unfair or deceptive trade practices."[43] Thus, prior to placing a health claim on a product, the FTCA requires that the manufacturer possess reasonable substantiation before

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[35] *See* 21 C.F.R. § 101.13(h)(1). The disclosure statement is required when a nutrient content claim is made and one of the following nutrients is present in the food in excess of the level listed: total fat, 13 g; saturated fat, 4.0 g; cholesterol, 60 mg; sodium, 480 mg. An example disclosure statement is "See nutrition information for total fat."

[36] *See id.* § 101.93(f).

[37] *See id.*

[38] *See id.* § 101.93.

[39] 21 U.S.C. § 343(a)(1) (2012).

[40] *See* U.S. FOOD & DRUG ADMIN., REGULATORY PROCEDURES MANUAL, PROCEDURES FOR CLEARING FDA WARNING LETTERS AND UNTITLED LETTERS, § 4.1 (July 2012), *available at* http://www.fda.gov/downloads/ICECI/ComplianceManuals/RegulatoryProceduresManual/UCM176965.pdf

[41] *See supra* note 19 and accompanying text (defining the food label/labeling). *But see* U.S. FOOD & DRUG ADMIN., MEM. OF UNDERSTANDING BETWEEN THE FED. TRADE COMM'N AND THE FOOD AND DRUG ADMIN., MOU 225-71-8003 (1971), *available at* http://www.fda.gov/AboutFDA/PartnershipsCollaborations/MemorandaofUnderstandingMOUs/DomesticMOUs/ucm115791.htm (last visited Sept. 25, 2013) (FTC and FDA agreeing that the FDA will exercise primary jurisdiction over food labeling).

[42] *See* U.S. v. 24 Bottles, 338 F.2d 157, 160 (2d. Cir. 1964).

[43] *See* 15 U.S.C § 45(a)(1) (2012).

making the claim to consumers.[44] The FTC uses a "competent and reliable scientific evidence" standard to determine if there is reasonable substantiation.[45] Similar to the FDA's response, if a manufacturer is suspected of not complying with the FTCA, the FTC will either send the manufacturer a warning or "informal inquiry letter," or serve the manufacturer with a subpoena or civil investigative demand.[46] Once the FTC confirms that the manufacturer has violated the FTCA, the FTC may take a number of different courses of action, ranging from seeking voluntary compliance through a consent order to filing a federal claim.

A. Front-of-the Package Labeling

Food manufacturers are required to place a nutrition label on the product, but they also typically place nutritional information on the front of the package, commonly referred to front-of-the package ("FOP") labeling. In 2009, Dr. Margaret Hamburg, the FDA Commissioner, revealed that the FDA would release proposed FOP labeling standards in which food manufacturers would be required to comply, if the manufacturer voluntarily chose to put nutrition information on the front of the package, with such proposed rules to be released within a few months.[47] Dr. Hamburg stated that the "vast array of different [front-of-package labeling] approaches is adding confusion rather than clarity."[48] Dr. Hamburg elucidated that manufacturers would likely be required to include information on saturated fat, salt, added sugar and calories, and mentioned the possibility of using Great Britain's traffic light labeling, where red, yellow or green dots are used to label the relative healthiness of food items.[49] Although the FDA announced in 2009 its intention to promulgate industry guidelines for FOP labeling, at this juncture, no such guidelines have been forthcoming.[50]

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[44] *See* FED. TRADE COMM'N, POLICY STATEMENT REGARDING ADVERTISING SUBSTANTIATION (1983), *available at* http://www.ftc.gov/public-statements/1983/03/ftc-policy-statement-regarding-advertising-substantiation.

[45] *See* In re Novartis Corp., 127 F.T.C. 580 (1999).

[46] *See, e.g.*, FED. TRADE COMM'N, FTC WARNS MARKETERS OF CHILDREN'S OMEGA-3 FATTY ACID SUPPLEMENTS THAT CLAIMS ABOUT BRAIN AND VISION BENEFITS MAY BE DECEPTIVEa (2010), *available at* http://www.ftc.gov/news-events/press-releases/2010/02/ftc-warns-marketers-childrens-omega-3-fatty-acid-supplements (discussing FTC's 11 warning letters sent to manufacturer of children's food supplements).

[47] *See* William Neuman, *F.D.A. to Clarify Standards for the Front of Food Labels*, N.Y. TIMES, Oct. 20, 2009.

[48] *See id.*

[49] *See id.*

[50] *See* U.S. FOOD & DRUG ADMIN., FDA'S MEDIA BRIEFING ON FRONT-OF-PACKAGE LABELING (Oct. 20, 2009), *available at* www.fda.gov/downloads/NewsEvents/Newsroom/MediaTranscripts/UCM187809.pdf

In response to the FDA's increased pressure to regulate FOP labeling, Congress, with the approval of the FDA, instructed the Centers for Disease Control and Prevention to partner with the Institute of Medicine ("IOM") to analyze FOP labeling.[51] This study was conducted in two phases, with the first phase focusing on current systems of FOP labeling, and the second phase focusing on the consumer perspective.[52] The first phase recommended that a FOP label should display calorie and serving size information, in an easy to understand format, such as "per serving" or "per package" instead of a technical measurement such as calorie content per grams.[53] In addition, the committee recommended that FOP labels include information on saturated fats, trans fats, sodium, calories, and serving size information.[54] Acknowledging the difficulty in developing a uniform FOP labeling system, the committee explored developing criteria for "nutrient specific systems" and "summary indicator systems" and suggested using consumer research to determine which system would work best.[55]

In its second phase, the IOM committee recommended "a fundamental shift in strategy" for FOP labeling to move beyond "simply informing consumers about nutrition facts" to actually encouraging consumers to make healthier food choices.[56] To accomplish this strategy, the committee recommended all products display a "simple, standard symbol" that conveys "calories per serving size in common household measures and points for saturated and trans fats, sodium and added sugars."[57]

(authorizing the FDA to (1) examine food labels for violations of current rules prohibiting false and misleading labels; (2) draft a new regulation providing a single set of science- and nutrition-based criteria for FOP labeling to ensure that consumers understand the actual healthfulness of food; (3) launch consumer research to determine the best method to convey information; and (4) work with industry regarding a single FOP symbol to enhance healthy choices).

[51] *See* INST. OF MED., EXAMINATION OF FRONT-OF-PACKAGE NUTRITION RATING SYSTEMS AND SYMBOLS, PHASE I REPORT 1 (Oct. 2010), *available at* http://www.nap.edu/catalog/12957/examination-of-frontofpackage-nutrition-rating-systems-and-symbols-phase-i.

[52] *See id.* "The committee's charge was to review front-of-package nutrition rating systems and symbols, identifying the systems developed by manufacturers, supermarkets, health organizations, and governments in the United States and abroad; evaluating the scientific basis of the underlying nutrient criteria; considering the strengths and limitations of various approaches; and planning a second phase of nutrition labeling to consider the consumer aspect of front-of-package systems." *Id.* at ix.

[53] *Id.* at 80-81.

[54] *Id.* at 81.

[55] *Id.* at 85. A "nutrient-specific system" would display the amount per serving of the nutrient; while the "summary indicator system" would use a single symbol to summarize the nutrient content of the product. *Id.* at 85-91.

[56] *See* INST. OF MED., FRONT-OF-PACKAGE NUTRITION RATING SYSTEMS AND SYMBOLS: PROMOTING HEALTHIER CHOICES 1 (2011), *available at* http://books.nap.edu/openbook.php?record_id=13221&page=R1.

[57] *Id.* at 4-5.

In 2010, Dr. Hamburg renewed her initiative to make "scientific accuracy and usefulness of food labeling one of [her] priorities. . . with the latest focus" on FOP labeling.[58] She announced her intent to "work closely with food manufacturers, retailers, and others in the design process," forecasting that new guidelines for calorie and nutrient labeling would soon be forthcoming from the FDA.[59] Under Dr. Hamburg's guise, the FDA sent warning letters to manufacturers concerning particular aspects of their labels that were "misbranded." Her examples of misbranding included:

- Nutrient content claims that FDA has authorized for use on foods for adults are not permitted on foods for children under two. . ..
- Claims that a product is free of trans fats, which imply that the product is a better choice than products without the claim, can be misleading when a product is high in saturated fat, and especially so when the claim is not accompanied by the required statement referring consumers to the more complete information on the Nutrition Facts panel.
- Products that claim to treat or mitigate disease are considered to be drugs and must meet the regulatory requirements for drugs, including the requirement to prove that the product is safe and effective for its intended use.
- Misleading "healthy" claims continue to appear on foods that do not meet the long – and well – established definition for that term.
- Juice products that mislead consumers into believing they consist entirely of a single juice are still on the market. Despite numerous admonitions from FDA over the years, we continue to see juice blends being inaccurately labeled as single-juice products.[60]

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[58] Letter from Margaret Hamburg, FDA Commissioner, to Food Industry (Mar. 3, 2010), *available at* http://www.fda.gov/Food/IngredientsPackagingLabeling/LabelingNutrition/ucm202733.htm (last visited June 10, 2013) [hereinafter Letter from Hamburg].

[59] *Id.*

[60] *Id; see also* Letter from FDA to Dreyers Grand Ice Cream, Inc. (Feb. 22, 2010), *available at* http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm202826.htm (warning that the "front panel shows that the product has no trans fat, but it doesn't have a disclosure statement to alert consumers that the product has significant levels of saturated fat and total fat); Letter from FDA to POM Wonderful (Feb. 23, 2010), *available at* http://www.fda.gov/iceci/enforcementactions/warningletters/ucm202785.htm (warning that the "product makes claims that it will treat, prevent, or cure diseases such as hypertension, diabetes, and cancer . . . [which] are not allowed on food products"); Letter from FDA to Ken's Food, Inc. (Feb. 22, 2010), *available at* http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm202830.htm (warning that "product

The FDA then reportedly accepted comments on FOP labels to assist in creating its new initiative.[61] The FDA stated that the FOP labeling requirements would initially be voluntary for food manufacturers, but would mandate the requirements if necessary.[62] However, since that time the FDA has yet to announce these voluntary guidelines for FOP labeling. In the meantime, despite the lack of oversight and regulation by the FDA, the food industry has proceeded to establish its own labeling scheme and is engaging in self-regulation.

B. FDA Too Overburdened to Regulate FOP Labeling

Broadly speaking, the FDA is the governmental agency charged with regulating food, drugs, cosmetics, medical devices, and tobacco.[63] As the agency tasked with so many diverse and wide-ranging areas, the FDA has a reputation for being overworked, underfunded, and incapable of effectively governing its responsibilities.[64] Within its food regulation context, the FDA oversees food labeling, as previously discussed. Some critics argue that the FDA has failed miserably in its plight for unambiguous, clear food labeling, especially in the area of FOP labeling.[65] These critics advocate for a uniform, mandatory FOP label that quickly conveys important nutrition information to consumers that is regulated by the FDA.[66] Yet the FDA's recent track record argues against assigning this overtasked

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makes claims such as 'Healthy Options,' but has more fat than is allowed in products labeled as 'healthy.'").

[61] *See* Letter from Hamburg, *supra* note 58.

[62] *Id.*

[63] *See* U.S. FOOD & DRUG ADMIN., ABOUT FDA, WHAT DOES THE FDA REGULATE, *at* http://www.fda.gov/AboutFDA/Transparency/Basics/ucm194879.htm (last visited Feb. 16, 2014).

[64] *See, e.g.*, Lydia Zurzw, *Taylor: FDA Needs More Resources for FSMA Implementation*, FOOD SAFETY NEWS, Feb. 6, 2014, *available at* http://www.foodsafetynews.com/2014/02/fda-needs-more-resources-for-fsma-implementation/#.UvcljfurF6M_(citing the FDA Deputy Commissioner for foods and veterinary medicine, Michael Taylor, as complaining that the FDA "cannot achieve [its] vision of a modern food safety system and a safer food supply without a significant increase in resources"); Kim Carollo, *FDA Rulemaking Process Lacks Transparency, Efficiency*, CARDIOVASCULAR BUSINESS, Feb. 5, 2014, *available at* http://www.cardiovascularbusiness.com/topics/healthcare-economics/fda-rulemaking-process-lacks-transparency-efficiency (underscoring the lengthy time period it takes the FDA to finalize rules for its regulation process – an average of 7.3 years); Barry Estabrook, *The FDA Is Out To Lunch*, Nov. 20, 2012, *available at* http://www.oncarth.org/article/out-to-lunch?page=1 (describing the FDA as lacking the "scientific capacity to perform its duties" and having "systematic problems . . .that threaten the health of anyone who consumes food in the United States").

[65] *See* Bruce Silverglade & Illene R. Heller, *Food Labeling Chaos the Case for Reform*, CENTER FOR SCIENCE IN THE PUBLIC INTEREST, at Part III-9 (2010).

[66] *Id.*

agency with another duty, *i.e.*, mandating a uniform FOP label and then regulating the compliance thereof.

For example, over the past decade, the front-page headlines demonstrate the FDA's ineffectual command in its regulatory areas, such as medical devices, dietary supplements and food safety.[67] As to medical devices, numerous devices have been recalled, with each recall furthering the public's incredulity that the FDA is capable of regulating such an important matter of public health.[68] One scholar called the FDA's oversight of medical devices "perhaps its worst period of regulatory failure."[69] The area of dietary supplements has suffered similar criticism, with even the FDA itself admitting that it "has limited resources to analyze the composition of food products, including dietary supplements. . ."[70] For food safety, critics claim the FDA lacks adequate resources to conduct food inspections, thereby leading to approximately 3,000 deaths per year.[71]

These deficiencies elucidate the public's well-founded perspicacity that the FDA is overburdened and incapable of effectively regulating yet another matter.[72] An additional recurring criticism of the FDA involves its entanglement with political ideologies, which are subject to change with each new administration. Examples of FDA actions ensuing based upon political motivations continue to proliferate.[73] Such subjectivity leads to inconsistent, capricious decisions at the whim of whichever political party is in power. The consumer, who likely lacks knowledge of the agency's

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[67] *See* James Walsh, *FDA Regulations Stifle Medical Device Industry*, J. SENTINEL, Feb. 17, 2013, *available at* http://www.jsonline.com/business/fda-regulations-stifle-medical-device-industry-8u8pfic-191504531.html; Sabrina Tavernise, *Groups Urge Action on Food Safety Law*, N.Y. TIMES, July 17, 2012, *available at* http://www.nytimes.com/2012/07/17/science/consumer-groups-criticize-delay-on-food-safety-law.html.

[68] *See* David C. Vladeck, *Preemption and Regulatory Failure*, 33 PEPP. L. REV. 95, 101-02 (2005) ("Daily front-page stories about harmful medical devices on the market such as defective Guidant defibrillators, Medtronic and Baxter infusion pumps, and Johnson & Johnson and Boston Scientific heart stents, raise serious questions about the ability of the FDA approval process to provide adequate assurance of safety by itself.").

[69] *Id.* at 126.

[70] Joseph K. Dier, *S.O.S. from the FDA: A Cry for Help in the World of Unregulated Dietary Supplements*, 74 ALB. L. REV. 385, 403 (2011) (discussing the FDA's slow action in removing Ephedra – 7 years – from the market, which allowed this dangerous product to be consumed by Americans for years).

[71] *See* Stephanie Armour, *Food Sickens Millions As Company-Paid Checks Find It Safe*, BLOOMBERG MARKETS, Oct. 10, 2012, *available at* http://www.bloomberg.com/news/2012-10-11/food-sickens-millions-as-industry-paid-inspectors-find-it-safe.html.

[72] *See, e.g.*, Joseph G. Hoflander, *A Red Bull Instead of A Cigarette: Should the FDA Regulate Energy Drinks?*, 45 VAL. U. L. REV. 689, 732-33 (2011) (citing the former FDA chief counsel as describing the FDA as a "paradigmatic example of the hollow government syndrome – an agency with expanded responsibilities, stagnant resources, and the consequent inability to implement or enforce its statutory mandates").

[73] *See, e.g.*, James T. O'Reilly, *Losing Deference in the FDA's Second Century: Judicial Review, Politics, and a Diminished Legacy of Expertise*, 93 CORNELL L. REV. 939, 978 (2008) (claiming that if the FDA was less politically motivated it might receive more judicial deference and positing that the that the delay in the availability of Plan B was due to the Bush administration's influence over the FDA).

arbitrariness, endures the consequences of the FDA's lack of perpetual lucidity and is bound by regulations that may or may not reflect the consumer's true desires. Thus, charging the FDA with the task of creating and policing a uniform FOP labeling system, when it cannot maintain its current regulatory obligations, seems unsound.

III. EXPLORATION OF SELF-REGULATION – BENEFITS AND DISADVANTAGES

A previous section of this article focused on government regulation involving food labeling.[74] At the other end of the government regulation spectrum lies self-regulation, a mechanism in which an industry, such as the food industry, independently develops rules and regulations to monitor its behavior without government intervention.[75] In some cases, self-regulation develops in response to public pressure or threat of increased government regulation.[76] Self-regulation and government regulation do not necessarily operate separately, but instead typically work toward the same goal.[77] Effective industry self-regulation occurs in many different areas, from forestry to attorneys to the food industry.[78]

Proponents of industry self-regulation claim that it has significant advantages over government regulation. For example, industry self-regulation can more quickly solve problems, using more innovative and malleable solutions than government regulation.[79] The primary reason for this increased speed and flexibility is because the industry itself determines its regulatory standards and when those standards have been breached, which leads to more knowledgeable persons, *i.e.*, experts in the

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[74] *See supra* Part II.

[75] *See* Tetty Havinga, *Private Regulation of Food Safety by Supermarkets*, 26 LAW & POLICY 515 (2006). Self-regulation is defined as a regulatory process whereby an industry-level . . . organization sets rules and standards . . . relating to the conduct of firms in the industry." Neil Gunningham & Jospeh Rees, *Industry Self-Regulation: An Institutional Perspective*, 19 LAW & POL'Y 363, 364 (2002). Typically, self-regulation is administered through industry associations or professional organizations. *See* Havinga at 517.

[76] *See* Lisa L. Sharma et al., *The Food Industry and Self-Regulation: Standards to Promote Success and to Avoid Public Health Failures*, 100 AM. J. PUB. HEALTH 240, 242 (2010).

[77] *See id.* at 242.

[78] *See, e.g.*, Havinga, *supra* note 75, at 517 (listing advertising standards, professional standards and futures market regulation as examples of self-regulated industries).

[79] FED. TRADE COMM'N & DEPT. OF HEALTH & HUMAN SERVS., PERSPECTIVES ON MARKETING, SELF-REGULATION & CHILDHOOD OBESITY, A REPORT ON A JOINT WORKSHOP 39 (April 2006) [hereinafter FTC PERSPECTIVES ON MARKETING]. The absence of government regulation does not mean industries are left to engage in bad behavior. Instead, "[m]any other controls, including social norms, civil litigation, and market forces such as fear of other reputational harm, help moderate firm behavior." Daniel Castro, *Benefits and Limitations of Industry Self-Regulation for Online Behavioral Advertising,* ITIF 2 (Dec. 13, 2011), *available at* http://www.itif.org/files/2011-self-regulation-online-behavioral-advertising.pdf.

industry with more insight, making the important decisions regarding the industry.[80] In complex environments that are ever-changing, self-regulation provides more adaptable and improved resolutions.

Additionally, when the big industry players band together, industry self-regulation creates peer pressure among the companies to abide by the self-imposed regulations or otherwise suffer the negative consequences.[81] These consequences could vary from consumer outcry to exclusion from industry trade groups, thereby ultimately leading to decreased profits.[82] Industry self-regulation could also lead to improved ethical standards that push companies to raise their ethics; whereas, when complying with government regulations, company conduct tends to meet the minimum threshold necessary to comply with the law.[83]

Although policymakers contend that regulation is needed to protect consumers, too much regulation exposes consumers to different risks.[84] For example, inefficient government regulation can merely increase a business's production costs, without producing a correlative benefit to the consumer who ultimately pays a higher price for the product.[85] Conversely, self-regulation, which does not solely involve the bureaucracy of government rulemaking and enforcement, tends to be more efficient, which ultimately benefits the consumer with lower prices and potentially superior goods or services.[86]

Self-regulation has numerous potential benefits, but there are also limitations to what self-regulation may achieve. One primary concern is the public's perception that industry lacks the necessary objectivity and transparency to effectively regulate themselves, with no accountability beyond the industry lines.[87] Instead, critics argue self-regulation serves only

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[80] *See* Gunningham, *supra* note 75, at 366.

[81] *See, e.g.,* Havinga, *supra* note 75, at 522-23 (explaining how all Dutch supermarket retailers require suppliers to comply with a food safety standard, which escalates the pressure on the retailers to comply with the standard, but at the same time creates a presumably safer product for the consumer).

[82] *See* Gunningham, *supra* note 75, at 403.

[83] *Id.* at 366.

[84] *See* Castro, *supra* note 79, at 5.

[85] *Id*; *see also* Saule T. Omarova, *Wall Street as Community of Fate: Toward Financial Industry Self-Regulation*, 159 U. PA. L. REV. 411, 422-23 (2011) (discussing "[a] key advantage of [self-regulation] is its diminished cost and increased efficiency").

[86] Castro, *supra* note 79, at 5; *see also* Havinga, *supra* note 75, at 519 (discussing how private regulation "[i]nvolves lower financial costs as well as allowing more freedom for citizens and organizations").

[87] *See* Michele Simon, *Can Food Companies Be Trusted To Self-Regulate? An Analysis of Corporate Lobbying and Deception to Undermine Children's Health*, LOY. 39 LOY. L.A. L. REV.169, 171 (2006) (listing the categories where food companies "have proven they cannot be trusted to serve children's best interests [through self-regulation] (1) lobbying to undermine school-based nutrition policies, (2) deceptive marketing of so-called 'healthier products,' and (3) misleading public statements of corporate marketing policies related to children").

one entity – the industry – at the public's expense.[88] Self-regulation, these critics argue, allows the industry to give the perception of adhering to strict standards, but in actuality is just a spurious attempt to deceive the public.[89] Moreover, because industry self-regulation in many circumstances is not transparent, the public may not be aware of any resulting industry punishment or sanctions for violating the private regulations.[90]

Instead, for self-regulation to be effective, the public's and private industry's interests must overlap in order to create the necessary balance of compulsion between the two competing groups; otherwise, the private industry lacks the incentive to abide by the self-imposed regulations.[91] In addition, the industry must develop its morality, "a set of industrial principles and practices that defines right conduct and spells out the industry's public commitment to moral restraint and aspiration."[92] With this morality in place, the industry next must establish policies and procedures that emphasize the industry's serious commitment to upholding standards idealized by the industry and the public.[93] But the mere existence of the policies and procedures is inadequate; instead, they must be implemented in a fashion that yields accountability and transparency to the public.[94] Without this transparency, the public remains incredulous and uncertain about the attainment of industry self-regulation.

But self-regulation is not a new concept; rather, it has been successfully employed in other industries for decades.[95] Analyzing an exam-

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[88] *See* Gunningham, *supra* note 75, at 366, 370.

[89] *See* Gunningham, *supra* note 75, at 366, 370 (citing John Braithwaite as saying "[s]elf-regulation is frequently an attempt to deceive the public into believing in the responsibility of a[n] irresponsible industry. Sometimes it is a strategy to give the government an excuse for not doing its job."); *see also* Simon, *supra* note 87, at 236 ("As long as the federal government maintains a hands-off policy and permits corporate self-regulation, there will be no accountability whatsoever.").

[90] *See* Gunningham, *supra* note 75, at 370.

[91] *See* Havinga, *supra* note 75, at 527-28 (discussing how food safety is important to "all parties," and for retailers the "interest . . . in safeguarding food safety is strongly related to their legal obligations, and to financial and reputational risks in case of food incidents," thus setting the appropriate stage for third party regulation).

[92] Gunningham, *supra* note 75, at 376.

[93] *Id.* at 381.

[94] *Id.* at 383 (stating that "[w]ith increasing transparency, in short, accountability is more readily maintained").

[95] For example, in the healthcare arena – an industry similar to the food industry in terms of public and private interests overlapping – self-regulation has been employed for decades to standardize the quality of medical care for hospitals. *See* Douglas Michael, *Federal Agency Use of Audited Self-Regulation as a Regulatory Technique*, 47 ADMIN. L. REV. 171 (1995). Founded in 1951, the Joint Commission, formerly known as the Joint Commission on Health Care and Accreditation of Health Organization, is a private voluntary accreditation organization that presides over the self-regulation of approximately 20,000 healthcare organizations, of which 5,400 are hospitals. The Joint Commission is governed by a group of 32 members comprised of "physicians, administrators, nurses, employers, a labor representative, quality experts, a consumer advocate and educators." *See* FACTS ABOUT THE JOINT COMMISSION, *at* http://www.jointcommission.org/facts_about_the_joint_commission/ (last visited Nov. 29, 2014). These

ple of self-regulation within the food context illustrates how it may work to better serve the public.

A. Self-Regulation of Food Advertising

In an area akin to food labeling – childhood food advertising – self-regulation has proven to be extremely effective. Recent studies reveal that childhood obesity rates are decreasing, but statistics show that a child who is obese has a significantly greater chance of continuing life as an obese adult.[96] Thus, the need to attack childhood obesity has become a central focus of lawmakers.[97] The cause of obesity may be due to numerous factors, from genetics to eating and exercise habits, but due to the potential causal connection between childhood obesity and watching television with the resultant commercials therein, a desire to control the content and quantity of such advertising has arisen.[98]

In 2006, the Council of Better Business Bureaus ("BBB") established the Children's Food and Beverage Advertising Initiative ("CFBAI") with the goal "to shift the mix of advertising primarily directed toward children to encourage healthier dietary choices and healthy lifestyles."[99] Currently, there are 17 companies that participate in the CFBAI, which comprise 80 percent of the marketing directed to children.[100] As participants in the CFBAI, each company develops its own pledge that responds to the CFBAI's "Core Principles."[101] Participants agree to be monitored

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professionals establish and enforce the standards of quality among the healthcare organization members. *Id.*

[96] *See* CTR. DISEASE CONTROL, PROGRESS ON CHILDHOOD OBESITY, *at* http://www.cdc.gov/vitalsigns/childhoodobesity/ (last visited Feb. 26, 2014) (acknowledging that many states have shown a decrease in childhood obesity rates, but highlighting the correlation between childhood and adult obesity).

[97] As part of an overall goal to reduce childhood obesity, in February 2010, First Lady Michelle Obama announced her "Let's Move Campaign," which sought to draw attention to this problem and encourage all interested parties – parents, lawmakers, food industry, consumer advocates, and children – to join in the effort to combat childhood obesity. *See* LEARN THE FACTS, ABOUT LET'S MOVE, *at* http://www.letsmove.gov/learn-facts/epidemic-childhood-obesity (last visited Feb. 26, 2014).

[98] *See, e.g.*, Tatiana Andreyeva et al., *Exposure to Food Advertising on Television: Associations with Children's Fast Food and Soft Drink Consumption and Obesity*, ECON. HUM. BIOLOGY 221, 231 (2011) (concluding that there is a causal relationship between food advertising and childhood obesity while emphasizing that "[i]n light of the epidemic of childhood obesity, continuing child exposure to advertising for nutritionally-poor foods is a serious public health concern").

[99] COUNCIL OF BETTER BUS. BUREAU, ABOUT THE INITIATIVE, *at* http://www.bbb.org/reno/programs-services/childrens-food-and-beverage-advertising-initiative/about-the-initiative/ (last visited Feb. 27, 2014).

[100] *Id.*

[101] Companies must agree to the following core principles:

- Devote 100% of their child-directed advertising to better-for-you foods, or to not engage in such advertising;

by the CFBAI, and if a company does not comply with its pledge, it is subject to removal from the program, with notification to the FTC of the company's expulsion.[102]

In 2008, the FTC assessed the CFBAI to determine whether this self-regulatory scheme was effective, and a follow-up assessment was conducted in 2012.[103] The results of the assessment showed that companies spent 19.5 percent less on advertising to children since the initiative began.[104] The 2012 report also showed that the nutritional profile of foods marketed to youth had "modest[ly]" improved within certain categories of food such as cereals, drinks, and fast food kids' meals.[105] And over the past decade, children have actually lowered their daily caloric intake, as

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- Establish nutrition standards, consistent with established scientific and/or government standards and recommendations and subject to BBB approval, that govern what foods they may advertise to children (new CFBAI-developed uniform nutrition criteria [went] into effect on Dec. 31, 2013);
- Limit the use of third-party licensed characters, celebrities and movie tie-ins in child-directed advertising consistent with the company's advertising commitment;
- Not pay for or actively seek to place their food and beverage products in the program/editorial content of any medium that is child-directed for the purpose of promoting the sale of those products;
- Include only the company's better-for-you foods or healthy dietary choices in interactive games that incorporate a company's food products; and
- Not advertise their branded foods to children in elementary schools (this limitation does not apply to charitable fundraising, displays of food products, public service messaging or items given to school administrators).

See COUNCIL OF BETTER BUS. BUREAUS, CHILDREN'S FOOD AND BEVERAGE ADVERTISING INITIATIVE PROGRAM AND CORE PRINCIPLES STATEMENT 1-3 (2010), *available at* www.http://cms-admin.bbb.org/storage/0/Shared%20Documents/Core%20Principles%20Final%20Letterhead%2012-2-09.pdf.

[102] Elaine D. Kolish & C. Lee Peeler, *Changing the Landscape of Food & Beverage Advertising: The Children's Food & Beverage Advertising Initiative In Action,* COUNCIL OF BETTER BUS. BUREAUS PROGRESS REPORT, at 5 (July 2008).

[103] FED. TRADE COMM'N, A REVIEW OF FOOD MARKETING TO CHILDREN AND ADOLESCENTS (Dec. 2012), *available at* http://www.ftc.gov/sites/default/files/documents/reports/review-food-marketing-children-and-adolescents-follow-report/121221foodmarketingreport.pdf [hereinafter FTC REVIEW OF FOOD MARKETING]. Between the 2008 and 2012 assessments, Congress directed the FTC, Agriculture Department, FDA and the federal Centers for Disease Control and Prevention to form a working group to develop uniform guidelines that restricted what foods could be marketed to children. The resulting proposed voluntary guidelines restricted advertisements to foods that included certain healthful ingredients and did not include unhealthful amounts of sugar, saturated fat, trans fat and salt. However, the guidelines were never implemented in response to complaints from the industry and some lawmakers. For example, David Boaz of the Cato Institute argued that the guidelines infringed on the industry's frees speech rights: "If the federal government decided to issue voluntary guidelines about what newsman should say to avoid inflaming the public, I think [the news media] would be pretty upset." *See* Ari Shapiro, *Obama Administration: Sugary Foods Not So Grrreat!*, NPR, Apr. 28, 2011, *available at* www.npr.org/2-11/-4/28/135809039/obama-administration-sugary-goods-not-so-grrreat.

[104] FTC REVIEW OF FOOD MARKETING, *supra* note 103, at ES-1. Most of the decreased spending came from decreased television advertising to children. *Id.* However, companies had increased spending in new forms of media, such as online marketing. *Id.*

[105] *Id.* at ES-2. Specifically, cereals had less sugar than in 2006 and more whole grain. *Id.* at ES-5.

well as their total consumption of fat, sodium and sugar.[106] According to FTC Chairman, Jon Leibowitz, "we're seeing promising signs that food companies are reformulating their products and marketing more nutritious foods to kids, especially among companies participating in industry self-regulatory efforts."[107]

B. Self-Regulation – Food Industry FOP Labeling

Within the food industry, self-regulation may be extremely beneficial to address industry activities that fall outside the authority of the FDA and FTC, such as dealing with activities that do not qualify as unfair or deceptive under government regulations.[108] Indeed, as admitted by the FTC and Department of Health and Human Services, "self-regulation can be a useful tool, as long as it is 'carefully tailored' to the problem at hand and there is no anti-competitive effect."[109] And where government mandated labeling runs the risk of violating First Amendment rights, industry self-regulation can address labeling issues without raising such concerns.[110]

A significant number of manufacturers are currently engaged in self-regulation in the area of FOP labeling. These manufacturers, instead of waiting on the FDA's FOP labeling guidelines, which were expected to have been released in 2010, have developed their own FOP labeling system.[111] In 2010, the Grocery Manufacturers Association ("GMA") and the Food Marketing Institute ("FMI") voluntarily developed a FOP labeling system called "Facts Up Front," which "is a fact-based approach that summarizes important nutrition information from the Nutrition Facts Pan-

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[106] *See* CDC PROGRESS ON CHILDHOOD OBESITY, *supra* note 8.

[107] Press Release, FTC Releases Follow-Up Study Detailing Promotional Activities, Expenditures, and Nutritional Profiles of Food Marketed to Children and Adolescents (Dec. 21, 2012), *available at* http://www.ftc.gov/news-events/press-releases/2012/12/ftc-releases-follow-study-detailing-promotional-activities.

[108] FTC PERSPECTIVES ON MARKETING, *supra* note 79, at 39.

[109] *Id.* at 39-40.

[110] *Id.*

[111] William Neuman, *Food Makers Devise Own Label Plan*, N.Y. TIMES, Jan. 24, 2011. This labeling system was devised due to the inability of the Obama Administration, the FDA and the food industry to come to an agreement on a front of package labeling plan. *Id.* Reportedly, the Obama Administration wanted the label to highlight the nutrients that consumers should avoid (such as sodium, calories and fat), while the food industry wanted to highlight the beneficial nutrients in the products (such as vitamins, minerals, and protein). *Id.* The Obama Administration felt that the food industry's suggested label would "be confusing, because [nutrients] would be included out of context, and it could make unhealthy foods appear like they had some redeeming quality. . . [Thus,] ice cream would be deemed healthy because it would have calcium in it." *Id.* When the food industry's ultimate labeling plan was unveiled – which did include beneficial nutrients – the Obama Administration called the plan "a significant first step" but cautioned that it would "look forward to future improvement" from the industry. *Id.*

Panel" and places this information in a multiple icon format on the front of the package.[112]

There are four basic icons – calories, saturated fat, sodium and sugars – that "are always presented together as a consistent set," except on small food packages where only one icon may be used due to space constraints.[113] Manufacturers also have the option to include two additional icons for particular nutrients – potassium, fiber, protein, vitamin A, vitamin C, vitamin D, calcium and iron – "if the product has more than 10 percent of the daily value per serving of the nutrient and meets the FDA requirements for a 'good source' nutrient content claim."[114] The purpose of the label is to "inform consumers about how key nutrients in each product fit in a balanced and healthy diet as part of the federal government's daily dietary advice."[115]

The GMA and FMI requested the FDA to exercise enforcement discretion of certain nutritional labeling regulations to facilitate implementation for Facts Up Front.[116] The GMA and FMI advocated that the Facts Up Front labeling were non-promotional disclosures, rather than nutrient content claims, thus not requiring the applicable disclosure statements required by the FDCA.[117] Alternatively, GMA and FMI requested that if the FDA determined that such disclosure statements were required, that the agency "exercise enforcement discretion to help ensure that food companies have no disincentives or barriers to rolling out the [Facts Up Front]

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[112] *See* GROCERY MFR. ASS'N, FACTS UP FRONT FRONT-OF-PACK LABELING INITIATIVE, *at* http://www.gmaonline.org/issues-policy/health-nutrition/facts-up-front-front-of-pack-labeling-initiative/ (last visited June 24, 2013) [hereinafter GMA FACTS UP FRONT]; *see also* ABOUT FACTS UP FRONT, *at* http://www.factsupfront.org/AboutTheIcons (last visited Feb. 28, 2014) (citing that the FMI "represents more than 1,500 food wholesalers and retailers").

[113] GMA FACTS UP FRONT, *supra* note 112.

[114] *Id.*

[115] *Id.*

[116] *See* U.S. FOOD & DRUG ADMIN., LETTER OF ENFORCEMENT DISCRETION TO GMA/FMI REGARDING "FACTS UP FRONT" (Dec. 13, 2011), *available at* http://www.fda.gov/Food/IngredientsPackagingLabeling/LabelingNutrition/ucm302720.htm. Specifically, the GMA and FMI requested discretion for:

> 1. Use of the four Nutrition Keys Basic Icons (calories, saturated fat, sodium, and total sugars), alone or accompanied by up to two Nutrition Keys Options Icons, without declaration of polyunsaturated fat and monosaturated fat in the Nutrition Facts panel as required by 21 C.F.R. 101.9(c)(2)(ii) and (iv).
>
> 2. Use of the four Nutrition Keys Basic Icons, unaccompanied by any Optional Icons, without the disclosure statement required by §1-1.13(h) when the nutrient content of the food exceeds specified levels of total fat, cholesterol, or sodium.
>
> 3. Use of the four Nutrition Keys Basic Icons, alone or accompanied by up to two Nutrition Keys Optional Icons, without disclosure of the level of total fat and cholesterol in immediate proximity to the saturated fat icon as required by §101.62(c).

[117] *Id.*

program on the labels of all eligible food products."[118] Although the FDA rejected GMA's and FMI's argument that the labeling did not involve nutrient content claims, it ultimately decided to exercise the requested enforcement discretion and "recognize[d] that the standardized, non-selective presentation of the four Basic Icons on a company's entire product line, if widely adopted by the food industry in a uniform manner, may contribute to FDA's public health goals by fostering awareness of the nutrient content of foods in the marketplace and assisting consumers in making quick, informed, and healthy food choices."[119]

Although some experts and nutritionists favor an FDA-mandated FOP labeling scheme, other nutritionists view Facts Up Front as an effective labeling system, even if not required by the FDA. For example, renowned nutritionist Bonnie Taub-Dix, describes Facts Up Front as follows:

> [It] is like a trailer to movie. It attracts you, teaches you something and then entices you to want to know more. You will have to flip the package over to get the rest of details from the Nutrition Facts Panel, especially if certain numbers, like cholesterol, personally call out to you.[120]

Recognizing that food labels can be confusing, she recommends that consumers review the Facts Up Front label to assist in determining whether a particular product is healthy for that individual.[121] And even though the Facts Up Front label does not indicate the healthfulness of the product by color coding (such as green for healthy products and red for non-healthy products), nutritionist Bonnie Taub-Dix says such color coding is too "simplistic" for food shopping where consumers have different needs.[122] The purpose of Facts Up Front is to assist consumers in making more educated nutrition decisions, which the program achieves.

Another example of a successful FOP labeling scheme can be found in powerhouse, mega-store, Walmart. Walmart, in consultation with food and nutrition experts from the public and private sectors, created the

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[118] U.S. FOOD & DRUG ADMIN., LETTER OF ENFORCEMENT DISCRETION TO GMA/FMI REGARDING "FACTS UP FRONT" (Dec. 13, 2011), *available at* http://www.fda.gov/Food/IngredientsPackagingLabeling/LabelingNutrition/ucm302720.htm.

[119] *Id.* However, manufacturers would still be required to include the disclosure statement on the front of package that referred consumers to the Nutrition Facts panel if an optional icon was included and if the product exceeded the disclosure trigger levels for total fat, saturated fat, cholesterol or sodium. *Id.*

[120] Bonnie Taub-Dix, *Just the Facts Up Front, Ma'am*, HEALTH & WELLNESS, May 2, 2013, *available at* http://health.usnews.com/health-news/blogs/eat-run/2013/05/02/is-the-facts-up-front-labeling-system-helpful.

[121] *Id.*

[122] *Id.*

"Great for You" food labeling scheme, which debuted in February 2012.[123] This scheme purports to allow "customers [to] instantly identify food options that are better for them."[124] If a food meets the "rigorous nutrition criteria" of the Great for You scheme, a green icon is placed on the front of the package for consumers, thereby theoretically allowing consumers to easily identify healthier food products.[125] The criteria are similar to the recommendations issued in the IOM report.[126] The icon appears on approximately 1300 of Walmart's foods and beverages and is available for private national brands that meet the nutritional criteria.[127]

Although Walmart has received praise from many sources, including First Lady Michelle Obama, about its healthy consumer initiative, nutrition experts question whether the scheme adds further chaos:

> It's been chaotic, with no oversight of any kind and very little scientific input, and companies just doing it in a way that benefits themselves and not the consumer. . . Now here comes Walmart, this massively powerful player, with yet another system. The question is, in the midst of all this clutter of competing systems, how helpful its approach is likely to be.[128]

Yet the ability of a "powerful player" like Walmart to proactively solve major issues, such as consumer healthiness, should not be underestimated.

Not all FOP self-regulatory labeling schemes have been as successful as the Facts Up Front system. In the summer 2009, a FOP labeling scheme called "Smart Choices" was announced that had been developed by a group of scientists, academicians, health and research organizations, and food and beverage manufacturers.[129] The goal of Smart Choices was

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[123] WALMART, GREAT FOR YOU, *at* http://corporate.walmart.com/global-responsibility/hunger-nutrition/great-for-you (last visited June 24, 2014).

[124] *Id.*

[125] *Id.* The scheme uses a two-step process, whereby step one "focuses on encouraging people to eat more fruits, vegetables, fiber-rich whole grains, low-fat dairy, nuts and seeds and lean meats," and step two "limits the amount of total trans and saturated fats, sodium and added sugars." *Id.*

[126] *See* IOM, *supra* note 56.

[127] *See* Press Release, First Lady Michelle Obama Celebrates Walmart's Progress on Making Food Healthier and More Affordable (Feb. 28, 2013), *available at* http://www.foodpolitics.com/wp-content/uploads/Walmart.pdf.

[128] Stephanie Strom, *Walmart to Label Healthy Foods*, N.Y. TIMES, Feb. 7, 2012, *available at* http://www.nytimes.com/2012/02/08/business/walmart-to-add-great-for-you-label-to-healthy-foods.html. *But see* Kathryn E. Hayes, Note, *Front-of-Package Nutrition Claims: Trustworthy Facts or Deceptive Marketing? Closing the Loopholes in Labeling*, 19 CARDOZO J. L. & GENDER 545, 561-62 (2013) (finding Walmart's Great for You labeling scheme to be "an improvement over 'Facts Up Front' and even closely resembl[ing] the IOM's recommendations").

[129] *See generally* Joanne R. Lupton et al., *The Smart Choices Front-of-Package Nutrition Labeling Program: Rationale and Development of the Nutrition Criteria*, 91 AM. J. CLIN. NUTR. 1078S, 1888S (2010) (reviewing the nutrient criteria and rationale for the Smart Choices program and concluding that it will present consumers with "science-based information on thousands of qualifying products that should assist in

to fill "the need for a single FOP nutrition labeling program that U.S. food manufacturers and retailers could voluntarily adopt to promote informed food choices and help consumers construct better diets."[130] Under this program, a manufacturer was allowed to place a green check mark with the wording "Smart Choices Program: Guiding Food Choices" if its product met specific nutritional criteria as developed by the Dietary Guidelines for Americans.[131] The labeling also included the calories per serving and serving per package information, which was placed alongside the Smart Choices logo, in an effort "to help people stay within their daily calorie needs and make it easier for calorie comparisons."[132]

However, Smart Choices' shelf life was relatively short. When certain products, such as Fruit Loops and Cocoa Puffs, appeared on shelves bearing the Smart Choices green check, consumers and public health advocates were outraged and took action.[133] In response to this criticism and the FDA's announcement that it would develop uniform FOP labeling criteria, the Smart Choices program was suspended.[134] Yet when discussing the suspension of the program, FDA Commissioner Hamburg acknowledged that even though "[t]his particular program may not have been the answer, . . . it is clear that a lot of people in a lot of places believe

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smarter food purchases."); Chelsea M. Childs, Note, *Federal Regulation of the "Smart Choices Program": Subjecting Front-Of-Package Nutrition Labeling Schemes to Concurrent Regulation*, 90 B.U. LAW REV. 2403, 2414-417 (2010) (discussing the Smart Choices program and advocating a uniform federal regulatory labeling scheme to bypass the current case-by-case label review conducted by the FDA).

[130] *See* SMART CHOICES PROGRAM, HELPING GUIDE SMART FOOD AND BEVERAGE CHOICES, *at* www.smartchoicesprogram.com (last visited Nov. 29, 2014).

[131] *See* NUTRITION CRITERIA, SMART CHOICES, *at* www.smartchoicesprogram.com/nutrition/ (last visited Nov. 29, 2014). The program created 19 different product categories with corresponding nutritional criteria for each. *Id.* To qualify for the program, a product had to meet the "nutrients to limit" benchmarks as well as include one or more "nutrients to encourage." *Id.*

[132] *See id.*

[133] The FDA initially sent a letter to the Manager of the Smart Choices program giving notice of its intent to closely monitor the program:

> [W]e will need to monitor and evaluate the products as they appear and their effect on consumers' food choices and perceptions. FDA and FSIS would be concerned if any FOP labeling systems used criteria that were not stringent enough to protect consumers against misleading claims; were inconsistent with the Dietary Guidelines for Americans; or had the effect of encouraging consumers to choose highly processed foods and refined grains instead of fruits, vegetables, and whole grains.

Letter from Michael R. Taylor to Sarah Krol (Aug. 19, 2009), *available at* http://www.fda.gov/food/ingredientspackaginglabeling/labelingnutrition/ucm180146.htm. Then, Congresswoman Rosa DeLauro, a Democrat from Connecticut, demanded the FDA investigate the program to determine whether the labeling was misbranded. Press Release, Rep. Rosa DeLauro, DeLauro Calls for FDA Investigation Into "Smart Choices" Labeling (Sept. 21, 2009), *available at* http://delauro.house.gov/index.php?option=com_content&view=article&id=236:delauro-calls-for-fda-investigation-into-smart-choices-labeling&catid=9&Itemid=25.

[134] *See* Press Release, Smart Choices Program Postpones Active Operations (Oct. 23 2009), *available at* http://www.smartchoicesprogram.com/pr_091023_operations.html.

that it is really important to devise ways to give consumers simple, easy-to-understand nutrition information on the front of food packages."[135]

Citing such examples as "Smart Choices," not all scholars are in agreement with the food industry's attempt to self-regulate food labeling issues.[136] Renowned nutritionist Marion Nestle strongly advocates against the food industry's perceived or actual participation in developing food regulations.[137] Instead, she and other scholars view food industry self-regulation with skepticism, by comparing the food industry's behavior to the tobacco industry where allegedly "programs and approaches that appear credible and are framed as in the public's interest but prevent legislation or regulation and damage public health."[138] Yet with the appropriate safeguards, even these skeptical scholars acknowledge that some food industry self-regulation has been effective with "the potential to benefit vast numbers of consumers."[139]

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[135] Speech, Margaret A. Hamburg, M.D., Commissioner of Food and Drugs - Remarks at the Nutrition Summit (Apr. 28, 2010), *available at* http://www.fda.gov/newsevents/speeches/ucm209954.htm.

[136] *See, e.g.*, Simon, *supra* note 87, at 171 (arguing that "food companies cannot be trusted, the government must step in to protect children's health"); Jennifer Pomeranze, *Front-of-Package Food and Beverage Labeling, New Directions for Research and Regulation*, 40 AM. J. PREV. MED. 382, 383 (2011) (stating that food manufacturers should not be allowed to develop their own FOP scheme , and instead, the FDA's FOP labeling guidelines – once they are announced – should not be "voluntary" but should be "mandated").

[137] *See* NESTLE, *supra* note 15, at 360-62.

[138] *See* Sharma, *supra* note 76, at 245; s*ee also* Dan Charles, *Can Big Food Kick Its Obesity Habit? Does It Really Want To?*, NPR, The Salt, Dec. 3, 2012 (discussing a debate between food industry and anti-industry players regarding the parallels between tobacco and the food industry and whether the food industry should be involved in policy-making discussions, where Derek Yach, the food industry proponent and former senior executive at PepsiCo, emphasized the importance of "more engagement, not less.")

[139] *See* Sharma, *supra* note 76, at 245. For food industry self-regulation to effectively protect public health, these scholars advocate several standards for self-regulation:

> (1) Transparent self-regulatory standards created by a combination of scientists (not paid by industry) and representatives of leading nongovernmental organizations, parties involved in global governance (e.g., World Health Organization, United Nations Food and Agriculture Organization), and industry; (2) No one party given disproportionate power or voting authority; (3) Specific codes of acceptable behaviors based on scientifically justified criteria; (4) Predefined benchmarks to ensure the success of self-regulation; (5) Mandatory public reporting of adherence to codes, including progress toward achievement of full compliance with pledges and attainment of key benchmarks; (6) Built-in and transparent procedures for outside parties to register objections to self-regulatory standards or their enforcement; (7) Objective evaluations of self-regulatory benchmarks by credible outside groups not funded by industry to assess health, economic, and social outcomes; (8) Periodic assessments/audits to determine compliance and outcomes; and (9) Possible oversight by appropriate global regulatory or health body (e.g., World Health Organization).

Id. at 241. These are laudable standards, but implementation within the food industry or any other industry seems difficult, not to mention that the standards straddle the line of government regulation by suggesting "oversight by an appropriate global regulatory or health body." Indeed, these scholars cite the forestry and fisheries industries as two examples where self-regulation "has been more successful," but neither of these industries appears to adhere to the standards.

IV. LITIGATION – COMPANION TO SELF-REGULATION

To those critics of self-regulation, who question whether food manufacturers can be trusted to monitor their own actions, it is important to emphasize that in most cases, manufacturers are not left to their own devices, without any checks and balances. Instead, consumers, through the pathway of the state consumer fraud statutes, retain power to ensure that manufacturers are held accountable. In the last few years, lawsuits have been increasingly filed against food manufacturers over advertising and labeling issues. In fact, this war against food manufacturers is being compared to the decades of litigation against "Big Tobacco," with suits being filed by similarly situated plaintiffs, such as consumers, consumer advocacy groups, as well as the government.[140]

A consumer in a typical suit against a food manufacturer argues that the food label was misleading and caused harm based on this misinformation.[141] In many such cases, plaintiffs' attorneys file suit after the FTC or the FDA has filed a complaint or sent a warning letter, respectively, to the manufacturer for allegedly violating the relevant labeling or advertising regulations – and a "piggyback" class action results.[142] The FTC will allege that either the manufacturer's advertising or labeling is misleading or that the manufacturer's claims about its products are not

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[140] *See* Stephanie Strom, *Lawyers From Suits Against Big Tobacco Target Food Makers*, N.Y. TIMES, Aug. 18, 2012; *see also* Jada J. Fehn, *The Assault on Bad Food: Tobacco-Style Litigation as an Element of the Comprehensive Scheme to Fight Obesity*, 67 FOOD & DRUG. L.J. 65, 74 (2012) (comparing food manufacturers to the tobacco industry and claiming they "should be held liable for creating social ills and exposing the public danger" and perhaps to a higher degree than the tobacco industry because tobacco is a "luxury item, food is a necessity").

[141] *See, e.g.*, Red v. Unilever, No. C 10-00387 JW, 2010 WL 3629689, at *1 (N.D. Cal. Sept. 14, 2010) (settling case based upon plaintiff's claim that product "I Can't Believe It's Not Butter" was "cholesterol free" was misleading because it contained hydrogenated vegetable oil). More broadly, consumer claims fall into two categories: 1) "all natural" cases where the consumer claims that the food manufacturer has advertised its product as containing all natural ingredients, when the ingredients are not; and 2) "health claims" cases where the consumer argues the manufacturer has advertised its product as having certain healthy qualities that are not accurate. *See, e.g.*, Anderson v. Jamba Juice Co., 888 F. Supp. 2d 1000 (N.D. Cal. Mar. 12, 2012)(filing suit based upon labeling of smoothie kit as "all natural"); Glover v. Ferrero USA, Inc., No. 3:11-cv-01086-FLW-DEA (D.N.J. Feb. 27, 2011)(challenging "nutritious" labeling of Nutella).

[142] *See* U.S. FOOD & DRUG ADMIN., REGULATORY PROCEDURES MANUAL, WARNING LETTER PROCEDURES, § 4-1-10 (2012), *available at* http://www.fda.gov/ICECI/ComplianceManuals/RegulatoryProceduresManual/ucm176870.htm. The warning letter to the manufacturer contains a request for correction and a request for written response within 15 days of receipt of the warning letter. *Id.* If the FDA is not satisfied with the manufacturer's response, the FDA may choose to take further action. *Id.* at § 4-1-8; *see also* Huey v. General Mills, Inc., No. 09-01368 (E.D. Cal. May 15, 2009) (filing class action suit less than two weeks after warning letter); Mason v. The Coca-Cola Co., No. 1:09-cv-00220 (D.N.J. Jan. 14, 2009) (filing class action suit approximately one month after warning letter); Katelyn DeRuyter, *Does Sackett Foreshadow the End of Non-Reviewability for FDA Warning Letters?*, 68 FOOD AND DRUG L. J. 241, 247 (2013) (summarizing how the FDA uses warning letters and the consequences that follow after issuance).

properly substantiated.[143] These piggyback class actions have increased in the last few years, but manufacturers have generally been successful at defending themselves.[144] This success is due in large part to the courts' recognition that a plaintiff's claim against a manufacturer cannot be based solely upon the manufacturer's alleged lack of substantiation for its product claims – there is no private right of action based upon an alleged violation of the FTC Act.[145]

But even without this private right of action, plaintiffs may file suit under the relevant state consumer protection statutes. States such as California and New Jersey are hotbeds for this litigation due to their favorable consumer protection laws.[146] For example, New Jersey's consumer fraud statute does not require a plaintiff to prove reliance; instead, a plaintiff must only prove an unlawful act with a resulting loss.[147] And California allows unlimited compensatory damages and substantial attorney fees.[148] Plaintiffs may prevail, either through settlement, injunctive relief or a trial verdict against the manufacturer. In most cases, the manufacturer must stop using the "misleading" advertising or labeling and must compensate plaintiff for his damages – *i.e.*, refund the purchase price of the product.

Lawsuits against food manufacturers have dramatically risen over the last few years, and although the overall impact of these lawsuits on food manufacturer's actions may not be obvious at first glance, the increase in suits has heightened manufacturers' sensitivity to the language used in food labeling and advertising and has led to changes by some

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[143] *See, e.g.*, In the Matter of POM Wonderful v. F.T.C. No. 9344 (May 17, 2012) (finding manufacturer did not have adequate support for its health claims and barring it from making such claims unless they were supported by two randomized, well-controlled, human clinical trials).

[144] *See, e.g.*, In re Cheerios Marketing & Sales Practices Litigation, No. 09-cv-2413, 2012 WL 3952069 (D.N.J. Sept. 10, 2012) (dismissing class action suits filed after warning letters issued because plaintiffs had not established injury-in-fact). The FTC is charged with protecting consumers from "unfair and deceptive trade practices." *See supra* Part II. As part of this protective power, the FTC ensures that manufacturers have "reasonable" substantiation for any product claims before the claims are made to consumers. As the connotation suggests, determining what encompasses "reasonable" substantiation is not well defined, but may require "competent and reliable scientific evidence."

[145] *See, e.g.*, Scheuerman v. Nestle Healthcare Nutrition, Inc., No. 2:10-cv-03684 (D.N.J. July 16, 2012) (granting summary judgment for manufacturer because plaintiff relied upon lack of substantiation rather than affirmatively proving that the claims were false).

[146] *See, e.g.*, Ogden v. Bumble Bee Foods LLC, No. 12-cv-1828, 2014 WL 27527 (N.D. Cal. Jan. 2, 2014) (denying in part defendant's motion for summary judgment and allowing plaintiff to proceed with California state law claims that Bumble Bee Foods mislabeled its fish products as to their omega-3 fatty acid content).

[147] *See* N.J. Stat. Ann. § 56:8-19 ("Any person who suffers any ascertainable loss of moneys or property, real or personal, as a result of the use or employment by another person of any method, act, or practice declared unlawful under this act or the act hereby amended and supplemented may bring an action or assert a counterclaim therefore in any court of competent jurisdiction.").

[148] *See* CAL. CIV. CODE § 1780(a), (e).

manufacturers.[149] For example, multiple lawsuits have been filed against the food manufacturer Snapple based upon its advertising of products as "all natural," even though the products contain high fructose corn syrup.[150] In response to this litigation, Snapple replaced the high fructose corn syrup with sugar.[151] Another example of manufacturer change in response to litigation occurred when a consumer filed suit against the manufacturer of Pure Via, a sugar-alternative sweetener, claiming that the sweetener contained ingredients that were not "natural" in contradiction of the product's labeling.[152] As part of the settlement agreement, defendant manufacturer agreed to change the product's labeling and marketing.[153]

The above examples of manufacturer change illustrate how litigation continues to alter food labeling. However, manufacturers – and their respective legal departments – seek to avoid large settlements or jury verdicts by avoiding litigation in the first place. Thus, to circumvent litigation, consumer satisfaction and careful attention to labeling continues to be the top priority. For example, Kraft altered the formulation of some versions of its macaroni and cheese to be healthier and to eliminate the use of artificial food dyes to create the pasta's orange color.[154] This alteration was conceivably in response to consumer outcry over the use of such color additives and the request for product change.[155] Other examples of recent manufacturer efforts to gratify consumers abound, and litigation's contributory cause thereto should not be overlooked.[156]

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[149] *See infra* note 156 (providing examples of voluntary changes). *But see* Fehn, *supra* note 140, at 70 ("Tort liability for the health consequences of high-caloric processed food, particularly on a large scale, could provide motivation for the food industry to stop exploiting consumers."). Within the food context generally, plaintiffs' attorneys followed a similar path back in the early 2000s when they filed suit against fast food restaurants, such as McDonalds, claiming that the restaurants failed to disclose the dangerous qualities of the food, including its allegedly addictive nature. *See Pelman v. McDonald's Corp.*, 237 F. Supp. 2d 512 (S.D.N.Y. 2003). Such suits were unsuccessful because plaintiffs had difficulty proving the all important element of causation, *i.e.*, that McDonalds was the but-for cause of plaintiff's obesity, when other factors such as lifestyle and genetics could not be ruled out.

[150] *See e.g.*, Stacy Holk v. Snapple Beverage Corp., 575 F.3d 329 (3d. Cir. 2009).

[151] *See* Nathan A. Beaver, *"Natural" Claims: The Current Legal and Regulatory Landscape*, 2012 WL 4971935, at 1, 7 (2012) (discussing how food manufacturers have altered their food labeling in response to threatened lawsuits and how Snapple specifically changed its product based upon such litigation).

[152] *See* Agular v. Merisant, No. 2:14-CV-00670 (C.D. Cal. Oct. 2, 2014) (order approving proposed settlement agreement).

[153] *Id.*

[154] Jacque Wilson, *Kraft Removing Yellow Artificial Food Dyes From Some Mac and Cheese*, CNN, Nov. 4, 2013, *available at* http://www.cnn.com/2013/11/01/health/kraft-macaroni-cheese-dyes/ ("The new versions [of Kraft macaroni and cheese] will have six additional grams of whole grains, be lower in sodium and saturated fat, and will use spices instead of artificial food dyes to recreate the pasta's famous yellow-orange color.").

[155] *See id.*

[156] *See, e.g.*, Kraft Singles to Lose Artificial Preservatives, USA TODAY, Feb. 10, 2014, *available at* http://www.usatoday.com/story/money/business/2014/02/10/kraft-singles-artificial-preservatives/5372883/ ("Consumers are looking for those less artificial cues and messages," said Gavin Schmidt, manager of

Against the backdrop of self-regulation, the option of pursuing a legal claim against manufacturers who mislead consumers through inaccurate labeling provides a safety net for consumers, giving consumers some level of power alongside the manufacturers. Thus, self-regulation does not operate in isolation; rather, in conjunction with litigation. The juxtaposition of these two mechanisms lends further credence to allowing food manufacturers the autonomous choice for FOP labeling decisions, without the need for FDA regulations.

V. FOOD INDUSTRY'S CONTINUED SELF-REGULATION

Various industries, from healthcare to forestry, have illustrated efficacious self-regulation.[157] Self-regulation may not be appropriate for all industries or even aspects of certain industries, but for food manufacturers' FOP labeling decisions, self-regulation is not only an effective method of regulation, but appears to offer advantages not presented by government regulation.

First, FOP labeling decisions create the necessary balance of compulsion between the public's interest and those of the food industry. The American consumer has become more educated the past couple of decades regarding food choices and the connection between food and health. As the consuming public continues to become more interested in healthier food consumption, the food industry to successfully compete in the marketplace must develop healthier products and label them accordingly. The food industry recognizes the importance of conveying healthful information to consumers as evidenced by its current FOP labeling scheme, Facts Up Front, which seeks to inform consumers of the nutritional information of its products in an easy to read format. Should manufacturers veer from

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cheese research and development at Kraft, because "[t]hose messages are more meaningful to consumers than they have been in the past."); David Pierson, *General Mills Drops GMOs from Cheerios*, L.A. TIMES, Jan. 3, 2014, *available at* http://www.latimes.com/business/la-fi-cheerios-gmo-20140104,0,4949616.story#axzz2tsklmYYt ("The company maintains that government-approved genetically engineered foods are safe to eat . . . [and] denied that outside pressure motivated the change [,and] [t]he only explanation given by company officials was that they believed the new formulation would be popular."); *Yoplait Yoghurt Making Headlines With Health News*, Market Watch, THE WALL STREET JOURNAL, Sept. 13, 2013, *available at* http://www.marketwatch.com/story/yoplait-yogurt-making-headlines-with-health-news-2013-09-13 ("Our consumers expressed their need for a product that doesn't contain high fructose corn syrup for their kids and we listened and acted,' said Justin Conzemius, Yoplait associate marketing director."); Stephanie Strom, *Food Companies Have Cut Back on Calories, Study Says*, N.Y. TIMES, Jan. 9, 2014, *available at* http://www.nytimes.com/2014/01/09/health/food-companies-have-cut-back-on-calories-study-says.html (reducing the amount of calories in their products, large food corporations may have reduced the average American's caloric intake by 78 calories a day).

[157] *See* Havinga, *supra* note 75, at 517.

providing truthful, accurate information, the consuming public not only has the option of legal redress, but also has the free market choice not to purchase those products, thereby burdening the company's potential profitability. These counterbalancing interests – those of the consumer and the food manufacturer – create the necessary pressure for the food manufacturer's current FOP labeling self-regulatory scheme to continue to work.

The food industry's current FOP labeling scheme, Facts Up Front, illustrates the industry's formulation of a set of principles that clearly defines its commitment to providing consumers with important nutritional information to aid in making healthier choices.[158] The hurried grocery shopper now has the benefit of viewing this information, *i.e.*, calories, saturated fat, sodium and sugars, on the front of a package, which ultimately saves the shopper valuable time from having to review the nutritional panel on the back of the product. And for those products that contain a nutrient that is more than 10 percent of the daily value per serving of the nutrient and meets the FDA's requirements, the manufacturer may include the respective icon for up to two nutrients. This labeling delivers valuable information in an easy-to-read format. So valuable, that even the FDA recognized how the labeling scheme would contribute to the FDA's goals of educating consumers about the content of food.[159]

The food industry has established policies surrounding its FOP labeling system, but the mere existence of these policies does not guarantee an effective self-regulatory scheme. In conjunction with the policies, the food industry must implement them with a high degree of transparency that commands respect from the public; otherwise, the public will lack confidence in the industry to self-regulate.[160] The Facts Up Front program was developed in the public eye and through the FDA's approval process. Not only was the approval process transparent, but the implementation of the program has been transparent as well. But, should a consumer question the accuracy of the food industry's labeling, he may pursue the legal route of filing suit under a state consumer fraud statute.[161] And the food industry remains not only accountable to the consumer, but is also answerable to the FDA or FTC for misleading labeling or advertising, either of which may result in the manufacturer being rebuked through various procedures.

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[158] *See supra* Part III.B.
[159] *See supra* text accompanying note 119.
[160] *See* Gunningham, *supra* note 75, at 366-67.
[161] *See supra* Part IV.

VI. CONCLUSION

Food manufacturers are currently engaged in self-regulation for their FOP labeling. Although the FDA announced several years ago that FOP labeling regulations would be forthcoming, to date, these regulations have not been announced. The FDA, an agency responsible for regulating the U.S. supply of drugs, medical devices, cosmetics, and tobacco products, is already overburdened. Since the food industry's labeling scheme effectively informs consumers about nutritional content of its products and consumers are not without any recourse should manufacturers mislead them, the FDA should focus its efforts on other areas where its regulations are necessary. Should the FDA decide to implement FOP labeling regulations that mandate requirements different from the manufacturer's current system, food manufacturers will be forced to re-label their products, thereby incurring expenses that will ultimately be passed on onto consumers in the form of higher prices for food products. Food manufacturers appear to understand that self-regulation is a privilege, not a right, and until their conduct reflects a deviation from this privilege, they should be allowed to continue on the self-regulation route.